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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,082	11/10/2000	Ian W. Hunter	1118/174	4206

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BOSTON, MA 02110-1618

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/06/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/710,082

Applicant(s)

Hunter

Examiner

Arlen Soderquist

Art Unit

1743



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 12, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17, 41, and 44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-17, 41, and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

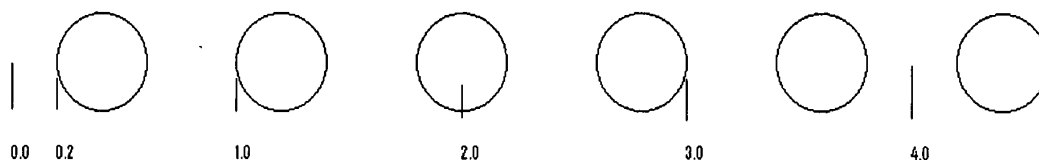
Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

1. Claims 1, 3, 5-15, 41 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 1, 14 and 41 the “density of at least 1 through-holes per square millimeter” does not have antecedent basis in the originally filed specification and the limitation is new matter. In particular examiner was not able to find any description in the specification of a minimum number of through-holes per area in the specification that would support a density of at least one through-hole per square millimeter. This is because the limitation includes one through-hole per square millimeter. Applicant points to sections of page 6 as basis for the limitation. Examiner attempted to determine the minimum density that would be clearly supported by this disclosure of specification. The minimum density would occur at the largest diameter and center-to-center spacing. The following diagram is based on a through-hole diameter of $400\ \mu\text{m}$ and a center-to-center spacing of $800\ \mu\text{m}$ as taught on page 6 of the specification. In the diagram the zero point is an edge and the numbers are in units of millimeters. The first through-hole is spaced 0.2 mm from the edge to provide a through hole that is not in any manner open to an edge. From the diagram it is clear that a repeating pattern occurs every 4 mm and that five through-holes are found in this distance. This provides a minimum density of 1.5625 holes per square millimeter. This is the minimum density that is fully supported by the specification. This density is over 56% greater than the “one through-hole per millimeter” that constitutes the minimum density required by claims 1, 14, and 41. This clearly shows that the full scope of the claimed “at least one through-hole per square millimeter” cannot be reached by the diameter and center-to-center spacing taught in the specification. Thus there is not support in the originally filed specification for the minimum density of holes being the “at least one through-hole per square millimeter” language of claims 1, 14 and 41.



2. Claims 14-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 14, step c is identical to step b which raises the question of how many times is the step to be performed. In claim 17 the scope of "at least one through-hole" is greater than the scope of claim 16 which requires a set of more than one through-hole to be illuminated and analyzed

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-15, 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario (US Patent 4, 682,890) in view of Davis. In the patent de Macario describes a carrier and a microsample holder (30) for use in horizontal beam spectrophotometers in place of conventional cuvette supports that normally are used with such spectrophotometers. The

microsample holder is formed as a plate having a number of retaining elements preferably in the form of a circular perforated areas for retaining drops of samples to be analyzed by the spectrophotometer. Columns 2-3 teach a sample holder of similar design is known for vertical beam spectrometers. Columns 7-8 teaches that the holder (30) is formed with a set of retaining elements, such as a row of four retaining elements (32,34,36,38). The retaining elements are of circular shape having diameters on the order of about 3 mm, each retaining element being capable of retaining a 5-10 μ l sample of liquid to be analyzed. The surfaces of holder (30) other than the circular areas may be coated with a thin layer of hydrophobic material to assure retention of the liquid samples within the circular areas. The circular hole diameter permits the surface tension of the liquid sample to retain that sample stably within the confines of the hole. The remainder of holder (30) need not be light transmissive, it is, nevertheless, advantageous to its construction to construct the plate of transparent material, such as glass, plastic, quartz or the like. The holder (30) may have two or more rows of retaining elements, if desired, such as the rectangular pattern shown in FIG. 5 and described in column 7, lines 45-61 or column 11, lines 6-28. It is recognized that the holder is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers to pass through the center of each sample retained by retaining elements. In this respect the paragraph bridging columns 7-8 teaches that since the overall height, length and width of the carrier are identical (or substantially identical) to the height, length and width of the conventional cuvette support, the carrier is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers. Thus, the retaining elements are aligned with the analyzing beam that normally passes through windows of the conventional cuvette support. It is seen that the analyzing beam thus passes through the center of each sample retained by retaining elements. The beam passes through only one sample at a time, and as the carrier is indexed, and successive samples are exposed to the beam. The patent also teaches that the de Macario device is meant to reduce the amount of sample required for the testing. The paragraph bridging columns 10-11 teaches the addition of reagents and samples to the holes of the device. The hole diameter, plate thickness and density of holes taught by de Macario are greater

than claimed, however the patent also teaches that the de Macario device is meant to reduce the amount of sample required for the testing.

In the patent Davis teaches a sample support for optical observation which is similar to that taught by de Macario. The drawings show a specimen tray or holder (1) to be employed for optical observation or analysis, and in particular for use in infrared microspectroscopy. The holder (1) includes one or more openings (2) and each opening is provided with an internal ledge or shoulder (3) and a specimen support (4) is supported on each ledge. Each support is preferably a disc-like member having a pair of generally flat, parallel, opposed surfaces and one or more unobstructed holes (5) extend through the support between the opposed surfaces. Each support is formed of a generally rigid material which will not be attacked by water or acids. Metals, such as stainless steel or gold; or plastic materials such as nylon, polytetrafluoroethylene (Teflon), or Kevlar, can be used to produce the support 4. As shown in the drawings, holes (5) are generally circular in cross section, but it is contemplated that the holes can have other cross-sectional configurations. Davis teaches that holes (5) have a diameter greater than 10 microns, generally in the range of about $10\mu\text{m}$ and 13 mm. The cross sectional area or diameter of the holes is correlated with the surface tension of a liquid specimen to be analyzed, such that a film (6) of the liquid will span or enclose the holes, as shown in figure 2. This is taught as being adjustable to provide a quality spectrum based on the thickness of the sample being investigated. Holes (5) can all be of the same diameter or cross-sectional area, or alternately as illustrated in figure 2, the holes can have different diameters. With different diameter holes, the thickness of the liquid film which bridges or encloses the holes will vary with the hole diameter, and thus the operator can select a film thickness to provide the best quality spectrum. By directing an infrared beam through the unsupported film in one of the selected holes, an infrared spectrum of the specimen can be generated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use smaller diameters within the range taught by Davis because of the ability to further reduce the sample volume and provide a quality spectrum using a single hole. Applicants are directed to the fact that the Courts have held the size of an article to be not a matter of invention;

the discovery of an optimum value of a known result effective variable without producing any new or unexpected results is within the skill of the routineer in the art; and mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art. See *In re Rose*, 105 USPQ 237 (CCPA 1955), *In re Boesch*, 205 USPQ 215 (CCPA 1980) and *In re Harza*, 124 USPQ 378 (CCPA 1960), respectively. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention was made to optimize a density of holes and hole dimensions in order to produce a film thickness that would provide a proper spectra as taught by Davis and to provide a sufficient amount of sample to detect.

5. Claims 16-17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario in view of Davis as applied to claims 1, 3-15, 41 and 44 above, and further in view of Böcker (US 5,786,226 newly applied). de Macario does not teach an array detector.

In the patent Böcker teaches quantitative transmission spectroscopy where a sample liquid is applied onto a sample carrier having a net in such a manner that the liquid spreads across the meshes of the net. The liquid on the net is exposed to radiation essentially perpendicularly to the net, and the transmitted radiation is detected. The net accomplishes a dosing of the liquid in such a manner that identical meshes include identical quantities of liquid. For a given net, it is possible to derive the amount of liquid, which is located in a mesh and accessible to radiation, from a net constant. Knowing the amount of liquid detected by the radiation, it is possible to use the radiation absorption to calculate the concentration of one or several analytes contained in the sample liquid. In column 5 lines 23-36, Böcker teaches the detection of samples in the filled meshes. The net of a sample carrier can be scanned with a light beam which is smaller than the cross section of the meshes similar to the detection method of de Macario. Detecting the transmitted light beam allows differentiating between liquid-filled and non-filled meshes. Advantageously, image recognition can be accomplished with a method where a light beam of a sufficient size is directed onto the net, and the transmitted radiation is detected with a CCD array. Based on the signals generated by the CCD array and using known algorithms for pattern detection, it is possible to distinguish between filled and unfilled meshes and to determine the number of filled meshes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the detector array of Böcker in the de Macario method because of the ability to use the detected signal to determine multiple sample containing positions without scanning which Böcker teaches as an advantage.

6. Applicant's arguments filed March 12, 2002 have been fully considered but they are not persuasive. Relative to the new matter rejection, paragraph 2 above, examiner has provided evidence that the specification as originally filed does not provide proper support for the currently claimed density limitations. Relative to the de Macario reference, applicant's comments are directed toward the wrong reference. It is US Patent 4,682,890 that is being used by examiner rather than US Patent 4,682,891 that applicant has quoted section from on page 5 of the response. When the proper reference is consulted there is a clear teaching of through-holes. Relative to the obviousness rejection, applicant is directed the fact the de Macario reference clearly shows that capability to place different samples in the different openings. This capability is not limited to the structure of de Macario, but would be recognized by one of skill in the art as being a capability of Davis that would result if an amount of sample were placed in each hole that did not exceed the volume of each hole. Thus Davis is clearly capable of having individual samples placed in each through-hole. Although the de Macario device is taught as intended to replace the conventional cuvette, the paragraph bridging columns 7-8 teaches that the retaining elements (holes) are positioned that they can be index either manually or automatically to present each of the retaining elements to the analysis beam of the spectrometer. This in combination with figure 5, column 7, line 45-61, and column 11, lines 6-28 of the de Macario patent, teaching that modifications include a two dimensional array of individual samples having "two, three or more rows of retaining elements" clearly show that de Macario contemplated more than the simple two row embodiment shown in figure 5. Additionally with either manual or automatic indexing, the amount of movement during the indexing step is not specified or limited in any manner by the patent. Thus spacings on the order of the Chang or Davis patents are not outside of the teachings of de Macario. Further the Davis patent which is subsequent to the de Macario patent shows that spectrometers had developed to the point that a single hole of the size taught by Davis could be

analyzed by that time. This clearly shows that by the time of Davis the art had developed to the point that the teachings of de Macario could be applied on a scale which was smaller than at the time of the de Macario patent. The secondary references are clearly within the scope of analogous art and as such provide reasons in combination with the de Macario patent for their use in the manner in which they have been applied.

Relative to the changes to claim 16 the Böcker reference teaches that use of a CCD array is advantageous compared to scanning over a two-dimensional array of sample filed openings (meshes).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional reference relates to using array detectors in measuring multiple sample containing wells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-

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305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

A handwritten signature in cursive script, reading "Arlen Soderquist".

May 3, 2002
ARLEN SODERQUIST
PRIMARY EXAMINER